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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,228	03/16/2004	Stefan Pulst	825466-100151	8912

34026 7590 08/15/2006

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EXAMINER
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BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/802,228

**Applicant(s)**

PULST, STEFAN

**Examiner**

Valarie Bertoglio

**Art Unit**

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-15 and 20-31 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8,11,12 and 16-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/16/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                         |                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____                                                |

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### **DETAILED ACTION**

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Valarie Bertoglio, Ph.D., Group Art Unit 1632.

Applicant's amendment dated 06/21/2006 has been received. Claims 1-8 and 16-19 have been cancelled. Claims 11,20-22,24 and 25 have been amended. Claims 9,10 and 13-15 are withdrawn as being drawn to a non-elected invention. Claims 9-15 and 20-31 are pending and claims 11-12 and 20-31 are under consideration in the instant office action.

#### ***Specification***

The objection to the specification is withdrawn in light of Applicant's amendment to the abstract.

#### ***Claim Objections***

The objection to claim 1 is withdrawn in light of Applicant's amendments to the claims.

#### ***Double Patenting***

The double patenting rejections are withdrawn in light of Applicant's cancellation of all relevant claims.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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The rejection of claims 1-8, 11, 12, 17-24 and 26 under 35 U.S.C. 101 is withdrawn in light of Applicant's amendments to the claims.

***Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 12 and 20-31 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is maintained for reasons of record set forth at pages 10-17 of the office action dated 01/17/2006.

Applicant's arguments have been fully considered and are partially persuasive with respect to certain aspects of the rejection. Applicant has amended the claims to more narrowly define the active method steps of the claims, addressing aspects relating to the extreme breadth as set forth at page 12 of the office action dated 01/17/2006. Other aspects of the rejection are maintained as set forth below.

The specification fails to enable the claimed invention because the specification does establish a clear nexus between over-expression of SCA-2, through administration of either nucleic acid encoding SCA-2 or direct administration of SCA-2 protein, and reduction or treatment of obesity in any organism. Neither the specification as filed nor the art of record at the time of the invention provide sufficient guidance to practice the claimed invention and an artisan

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of skill would have required extensive experimentation to carry out the claimed invention. Such experimentation would be undue because of the unpredictability of the role of SCA-2 in regulating obesity, the unpredictability of treating obesity by administering a SCA-2 therapeutic comprised of a nucleic acid encoding any SCA-2 protein or variant thereof from any species, the unpredictability of obesity and the influences of genetic background and environment, and the unpredictability of *ex vivo* or *in vivo* gene therapy in general. The specification does not provide sufficient guidance to address these issues for an artisan to practice the claimed invention (see pages 13-17 of the office action dated 01/17/2006).

Applicant argues that the experimentation required to practice the instant invention is neither complex nor undue (page 9, paragraph 2 of Applicant's Remarks). To attest to this, Applicant has submitted a declaration by Dr. Pulst. The Pulst declaration under 37 CFR 1.132 filed 06/21/2006 is insufficient to overcome the rejection of claims 11, 12 and 20-31 based upon a lack of enabling disclosure as set forth in the last Office action because: paragraphs 5-7 outlining the experimental setup to determine the effect of SCA-2 administration on the mouse model for obesity are prophetic teachings that fail to overcome the unpredictability in the art of gene therapy. Furthermore, the genetic linkage data that correlates obesity traits to the same region of chromosome 12 as the SCA-2 locus described at paragraph 11 of the declaration fails to establish a role for SCA-2 in metabolism or feeding behavior. This evidence fails to rule out a role for SCA-2, however, genetic linkage alone does not overcome a need for a functional link and merely established SCA-2 as a candidate gene.

Applicant argues that the observed obese phenotype in SCA-2 deficient mice occurs in a mixed genetic background. In response, having a mixed genetic background does not overcome

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the genetic background effects on obesity and body fat composition. Genetic background effects are often observed as a result of “hitchhiker” loci that are closely linked to the gene disruption and fail to segregate from the disrupted locus. An interaction between these loci is unlikely to be resolved through outcrossing. Regardless, the genetic background effects on obesity and body fat composition merely highlight the need for additional characterization of the SCA-2 deficient mouse and the role of SCA-2 in obesity to define a link between SCA-2 and obesity. More essential to the claimed subject matter is that not only has a role for SCA-2 been linked to obesity in humans, the specification and the art of record has provided no evidence whatsoever that obesity, body fat, or feeding behavior can be modulated by the introduction of exogenous SCA-2. The association of loss of gene function with a particular phenotype does not necessitate that a gain of function will cause the opposite phenotype. Moreover, there is no evidence that the obesity in a human that is not caused by a disruption of SCA-2 would be remedied by increasing SCA-2 as encompassed by the claims.

Applicant argues that a blanket rejection based on the unpredictability of gene therapy is inappropriate since many conditions have been shown treatable by gene and/or protein delivery approaches and that gene therapy has made considerable progress in recent years (paragraph bridging pages 10-11 of Applicant’s Remarks). In response, it is agreed that many advances in gene therapy have been made, however, these advances do not overcome the lack of guidance given by the specification with respect to how SCA-2 functions in obesity. For example, given the teachings of the specification, one of skill in the art would not know in which tissues to express the SCA-2 gene to remedy obesity. Determining this alone would require detailed expression and functional analysis just to determine which vectors and routes of administration

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one might attempt. This, along with no indication that introduction of exogenous SCA-2 will have any effect on obesity, renders the specification deficient in enabling the claimed invention

Applicant argues that it is not the overexpression of SCA-2 that is expected to yield a therapeutic benefit, but is the correction of a deficiency. In response, obesity in humans has not been linked to a deficiency in SCA-2. Furthermore, introducing a gene via viral vector is not necessarily a remedy for a disruption of an endogenous locus. Exogenous, viral encoded SCA-2 is not a replacement for genetic interactions that occur in a wild-type cell. Without demonstrating a functional restoration of the deficiency, it cannot be predicted that exogenous SCA-2 will restore a wild-type phenotype or provide even a partial therapeutic benefit.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 20-22 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's arguments have been fully considered but are not persuasive.

With respect to the rejection of claims 11, 20 and 25 as being incomplete, Applicant argues that the claims have been amended to recite a positive method step. This is not effective in overcoming the rejection as the claims continue to lack a positive process step that clearly relates back to the preamble. The claim fails to require that obesity be treated. Therefore, it is

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unclear how the step of administration of said pharmaceutical composition relates to the method for treating obesity and whether the goal of said method has been resolved.

The rejection of claims 2, 21 and 22 for lacking antecedent basis for terms recited in the claims is withdrawn.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejections of claims 1-8, 16-19 under 35 U.S.C. 102(b) as being anticipated by Pulst et al (U.S. Patent 6,515,197 B1 issued 2/4/2003) and by Pulst et al (WO 97/42314, 11/13/1997) are withdrawn in light of Applicant's cancellation of the claims.



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***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio  
Examiner  
Art Unit 1632

*Anne-Marie Falk*

ANNE-MARIE FALK, PH.D  
PRIMARY EXAMINER